

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK) Redacted Version
THIS DOCUMENT RELATES TO ALL CASES	

**PLAINTIFFS' RESPONSE IN OPPOSITION TO TEVA DEFENDANTS'
OMNIBUS MOTIONS IN LIMINE**

Plaintiffs file this response in opposition to Teva's omnibus motions in limine (ECF 2644).

I. ARGUMENT

Teva's motion is a transparent effort to whitewash certain relevant, probative evidence of its activities, to avoid the jury's rightly seeing as a whole Teva's overall lack of cGMP diligence, and broad cGMP deviations.

The Court should deny Teva's motions in limine opposed by Plaintiffs, and caution Teva that to the extent Plaintiffs indicate that they do not intend to insert specified evidence or argument in the first instance, that such evidence or argument may be permitted if Teva 'opens the door.'

A. Teva's Motion to Preclude the Toxikon Report

Teva and other TPP Trial Defendants have repeatedly argued—most recently

in their summary judgment papers—that prior to the 2018 recalls, NDMA’s properties made it very difficult to find (*see, e.g.*, Defs.’ Summ. J. Mem. (2562-1) at 16); and that new capabilities had to be built out by Defendants to detect and measure NDMA because existing capabilities could not detect NDMA. *See, e.g.*, Baertschi Merits Rpt. at ¶¶ 14, 38 (Ex. 12 hereto).

Yet, approximately four years prior to the recalls, in 2014, Teva had commissioned a packaging supplier to test rubber stoppers *explicitly* for NDMA and NDEA. *See* Teva Mot. Ex. A. This highly relevant testing, summarized in the Toxikon Report that is the subject of Teva’s motion, reveals (i) Teva’s knowledge and notice of NDMA and NDEA [REDACTED]; (ii) that testing capabilities and methods [REDACTED]; (iii) that, indeed,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]; and (iv) the [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]). *See id.*; *see also* Teva Mot. at 5 (arguing Teva’s VCDs [REDACTED]

[REDACTED]). All of this goes to Teva’s notice, knowledge, and capabilities, irrespective of whether the stoppers actually

contained NDMA. To the extent necessary, the report could also be redacted to limit to the directly relevant points when used at trial.

The Toxikon Report is relevant, and is not unfairly prejudicial.

B. Teva's Motion to Preclude Its Health Hazard Assessment ("HHA") and Drafts Thereof

The Court should summarily deny Teva's motion to preclude Teva's HHA and drafts thereof. These documents specifically relate to Teva's analysis of NDMA detected in ZHP's valsartan API. These documents touch on so many highly relevant points at issue for the upcoming trial there are almost too many to list. In the first five sentences alone, these documents confirm (i) NDMA [REDACTED]

[REDACTED], (ii) NDMA is [REDACTED]

[REDACTED], (iii) of the [REDACTED]

[REDACTED], (iv) the NDMA was

[REDACTED] (v) NDMA

results [REDACTED] and (vi) a [REDACTED]

[REDACTED]

[REDACTED]. *See* Teva

Mot. Exs. E-F, H. The foregoing alone, from just the first paragraph of the first page of the draft and final HHAs, establishes these documents' highly probative nature.

Defendants also have made clear they intend to minimize the characteristics of NDMA, referring to it variously as a "trace" substance that did not impair the

safety or efficacy of VCDs. Teva's HHA and drafts thereof refute this. These documents confirm that NDMA is a [REDACTED] that NDMA also [REDACTED] that [REDACTED] [REDACTED]; and that (as Plaintiffs rightly argue throughout this litigation) the [REDACTED] [REDACTED]. *Id.* Additionally, in other documents Teva omits from its motion, Teva's inhouse toxicologist wrote that NDMA was a [REDACTED] [REDACTED], *e.g.*, TEVA-MDL2875-00020519 (Ex. 13 hereto). Yet, in Teva's final HHA, the head toxicologist's language was altered by an unknown person, changing [REDACTED] [REDACTED] *compare id., with* Teva Mot. Exs. E-F, H. Teva inexplicably carried over the watered-down and misleading [REDACTED] [REDACTED] " *See, e.g.*, Barreto Dep. Vol. I at 172:15-176:6 (Ex. 14 hereto).

Simply put, that Teva dislikes a couple of sentences written by Teva's own employees in Teva's own business records (*see, e.g.*, Teva Mot. at 4-5) is not sufficient to preclude Teva's HHA and drafts thereof, which are highly probative of numerous issues for trial.

C. Teva's Motion to Preclude the FDA's Recission Letter About Teva's Use of Adulterated Valsartan API from Dr. Reddy's Laboratories

This Teva-specific motion in limine appears to overlap with motion in limine #2 in Trial Defendants' omnibus motion regarding unrelated regulatory actions. Here though, Teva specifically and improperly asks this Court to preclude a highly relevant letter from the FDA to Teva about Teva's unsuccessful attempt to sell adulterated valsartan product containing valsartan API from a non-party, Dr. Reddy's.

In short, in 2015, the FDA had found that Dr. Reddy's valsartan API facility was [REDACTED]. [REDACTED]. *See* Teva Mot. Ex. I. Teva had been using [REDACTED]. [REDACTED]. *Id.* The FDA rescinded Teva's ANDA for this valsartan, meaning Teva could not sell it, because of the underlying cGMP violations at Dr. Reddy's and the [REDACTED]. [REDACTED].

Teva's response demonstrates a deficient approach to cGMP and quality—the exact issues here. Teva argued to the FDA then, as it now argues here, that Teva's own testing of [REDACTED]. Teva also argued to the FDA, as it also now argues here, that Teva's audits of Dr. Reddy's [REDACTED]. [REDACTED]. *Id.* The FDA forcefully rebuked both of Teva's arguments. The agency informed Teva as follows:

[REDACTED]

Id. (emphasis added). As to Teva's own audits finding Dr. Reddy's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *Id.*

Plaintiffs do not intend to prove that Dr. Reddy's valsartan API, or Teva's finished dose incorporating same, was adulterated. Nor do Plaintiffs seek damages from Teva for valsartan containing API sourced from Dr. Reddy's. However, the FDA's recission letter to Teva in 2015, three years before the 2018 recalls, is highly probative, important evidence of Teva's notice and knowledge of what was and was not acceptable, including that [REDACTED]

[REDACTED]

[REDACTED]. The letter similarly demonstrates Teva's notice and knowledge that cGMP violations can exist at an API supplier even if [REDACTED]

[REDACTED] Even if the Court were to question the admissibility of

the letter in a vacuum, it is clear that Teva will open the door to the issues addressed therein.

D. Teva’s Motion to Preclude an Internal 2017 Email Chain (the “Bogoslavski Email Chain”)

The “Bogoslavski Email Chain” is a 2017 internal email chain amongst Teva scientists. *See* Teva Ex. L. In this email, Teva personnel specifically discuss [REDACTED]

[REDACTED]

[REDACTED], *see id.*, [REDACTED]

[REDACTED]. Notably, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See, e.g.*, TEVA-MDL2875-00049024 (Ex. 15 hereto).

The Bogoslavski Email Chain shows that Teva’s own personnel had [REDACTED]

[REDACTED]

[REDACTED]. This directly implicates Teva’s admitted duty to audit its supplier ZHP, and to be vigilant where deficiencies were routinely seen, which Teva failed to do. Of ZHP’s report, they said: [REDACTED]

[REDACTED] *See* Teva Mot. Ex. L. Teva’s personnel also noted myriad worrisome technical deficiencies, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* As to certain solvents, [REDACTED]

[REDACTED] *Id.* At the end,
they conclude that [REDACTED] *Id.*

The best Teva can muster against this highly relevant document is that it falls outside the scope of Magistrate Judge Schneider’s discovery ruling. Even though this quite obviously was not an *evidentiary* ruling, Teva argues, with no support or citation, that the Bogoslavski Email Chain relates to valsartan API “that was never sold in the United States.” *See* Teva Mot. at 8.

As an initial matter, Teva’s unsupported assertion about where product incorporating this API was sold is incorrect. More saliently, Magistrate Judge Schneider never limited discovery in the way Teva suggests. He specifically allowed “foreign discovery” of documents “regarding potential or actual nitrosamine contamination,” as well as “documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan.” ECF 303 (11/25/19 Order). The Bogoslavski Email Chain explicitly relates to

[REDACTED]

[REDACTED]. This goes directly to Teva’s notice and knowledge about the issues with ZHP’s valsartan API. At a minimum, it shows Teva’s awareness of highly relevant, serious cGMP deviations at ZHP as to valsartan API.

E. Teva's Motion to Preclude Emails Between ZHP and Teva About ZHP's DMF (the "Guda Email Chain")

One of Teva's repeated, albeit non-dispositive, refrains is that it had no access to the "closed" portion of the Drug Master File ("DMF") for ZHP's valsartan API. *See, e.g.*, Williams Merits Rpt. at ¶ 38 (Ex.16 hereto) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

(emphasis added)); Karlsson Dep. at 36:5-9 (Ex. 17 hereto) (claiming [REDACTED]
[REDACTED]s). Teva perennially raises this argument to suggest that it had no way of analyzing the DMF for ZHP's valsartan API in more detail.

Teva's own ordinary-course business records rebut these arguments. In May [REDACTED]
[REDACTED]. *See* Teva. Mot. Ex. M. Teva first requested [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] *Id.* (emphasis original). And this could have been done at any time, including years before. If Teva is claiming lack of access to the information in the DMF, then this evidence is on-point in refuting that claim.

Clearly this relevant email chain is admissible for numerous reasons. The email chain itself is a routine business record, which in turn contains party-opponent admissions by Teva's and ZHP's respective quality and regulatory affairs personnel. *See, e.g., MGM Studios, Inc. v. Grokster, Ltd.*, 454 F. Supp. 2d 966, 974 (C.D. Cal. 2006) ("All emails sent from that [defendant's corporate email] address are thus admissible non-hearsay as admission by the party opponent under Rule 801(d)(2)."); *see also, e.g., United States v. Lingala*, 91 F. 4th 685 (3d Cir. 2024) (defendant's and co-conspirator girlfriend's statements in love letters non-hearsay admissions as each was party-opponent).

The email chain rebuts Teva's defense that it had no access to an API supplier's DMF, or Teva's assertion that it never asks suppliers for the DMF. The email chain also implicates Teva's own lapses in quality oversight, insofar as Teva inspected ZHP's valsartan API facility in China [REDACTED]

[REDACTED]

[REDACTED]. *See* TEVA-MDL2875-0399168 (Ex. 18 hereto).

F. Teva's Motion to Preclude An Internal Email Critical of Teva's Quality Process (the "Karlsson Email")

Stefan Karlsson is a current Teva employee with nearly twenty years of API sourcing experience. *See* Ex. 20 hereto. He began working for Actavis in 2005, and continued with the firm through its acquisition by Teva in 2016, and has remained with Teva to the present. *Id.* He focuses on sourcing API for Actavis and Teva

products sold in the United States and elsewhere, including review of regulatory files and approvals for API, which includes Drug Master Files (“DMFs”). *Id.* Significantly, Mr. Karlsson was [REDACTED]. [REDACTED]. *See, e.g.,* TEVA-MDL2875-00640935 (Ex. 20 hereto). He actually [REDACTED]. [REDACTED]. *Id.*

Teva focuses on a singular email sent by Mr. Karlsson in October 2018, in which he outlines points for an upcoming global procurement meeting. *See* Teva Mot. Ex. O. His email does not discuss any “subsequent remedial measures” as contemplated by Fed. R. Evid. 407. Rather, it sets forth a number of highly relevant facts about Teva’s *existing* practices as they were at the time of the preceding recalls. This includes the fact that Teva (i) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] *Id.* Further, the email states that [REDACTED]

[REDACTED]. *Id.*

These candid recitations of the deficiencies in Teva’s quality oversight and related practices as to API procurement, including specifically how they contributed

to Teva's not catching the NDMA risk sooner, go to the state of Teva's practices earlier, not a *subsequent* measure taken. See, e.g., *McDaniels v. City of Phila.*, 234 F. Supp. 3d 637, 650 (E.D. Pa. 2017) (Rule 407 only extends to "measures that 'are taken,' not those that are merely hypothetical").

Moreover, everything that followed the recalls was a result of the FDA requiring that action, rather than purely voluntary efforts, so none of that can be a subsequent remedial measure by definition. See, e.g., *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 30393 n.542-303 (E.D. Pa. 2016) (denying motion to preclude evidence of drug labeling change because it was not entirely "voluntary"); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & PMF Prods. Liab. Litig.*, No. 03-cv-10012, 2011 WL 6740391, at *8 (S.D. Ill. Dec. 22, 2011) (denying request to preclude cessation of drug marketing at request of FDA, as FDA 'request' was "part and parcel to the enforcement mechanism of the FDA" and was "no more voluntary than a party paying a judgment without the judgment creditor pursuing post-judgment relief such as garnishment").

Moreover, under Rule 407, Plaintiffs are permitted to rebut Teva's likely argument that it could not have discovered the NDMA sooner, or to present the email for impeachment purposes. See, e.g., *In re Tylenol*, 181 F. Supp. 3d at 302-303 (denying motion in limine to preclude post-accident labeling change under Rule 407 because, among other things, evidence of subsequent change rebuts defense

argument that change prior to decedent's death was not possible).

Finally, that the email may reflect Mr. Karlsson's "personal views" (Teva Mot. at 12) is of no moment. He is a procurement professional with 20+ years of direct experience evaluating and sourcing API for Teva and its predecessor company Actavis. For present purposes, all that matters is that the email is a business record reflecting a party-opponent admission.

G. Teva's Motion to Preclude Its Own SOP on Contract Manufacturers

Teva has an SOP (CORP-0046) that specifically relates to "(Outsourced Activities) Contract Manufacture and Analysis." Teva Mot. Ex. Q. This SOP sets forth certain requirements Teva's own personnel should adhere to when dealing with or overseeing third-party manufacturers. ZHP made valsartan API (a "drug substance") for Teva's at-issue finished dose valsartan (a "drug product").

Teva disingenuously suggests that a contract manufacturer (manufacturing for Teva per Teva's own specifications - per Teva's stated interpretation) would be addressed differently from an API manufacturer like ZHP. Teva 30(b)(6) witness Daniel Barreto made clear that the requirements of the SOP were applied equally in practice to either, thus the SOP is clearly relevant in laying out Teva's own understanding of its cGMP obligations: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 14 (Daniel Barreto 4/14/21 Dep. Tr. at 58:23-60:14).

Moreover, Plaintiffs dispute Teva's interpretation as to the scope of applicability of the SOP as well. CORP-0046 on its face defines [REDACTED]

[REDACTED]” Teva Mem. Ex. Q (emphasis added). [REDACTED]

[REDACTED] within the scope of CORP-0046. *Id.*

Teva can try to rebut or respond to the evidence of this SOP, but it is clearly relevant and applicable here.

H. Teva's Motion to Preclude References to Teva's India Unit—Which Also Made Valsartan API

Teva admits that Teva's India facility made valsartan API during the relevant time period. While Teva did not incorporate that API into finished dose valsartan to be sold in the United States, Teva's own expertise with manufacturing valsartan API is relevant to Teva's notice and knowledge about myriad issues relevant in this trial, including (i) Teva's capabilities and methods for testing valsartan API, and (ii) the chemical route of synthesis for the valsartan molecule (the active ingredient itself in all valsartan API). For instance, by way of example only, Teva has argued that it lacked the capabilities to perform gas chromatography testing of ZHP's valsartan API, or was unaware of the need or ability for such testing. But Teva's own India

facility (at which Teva made its own valsartan API) [REDACTED]

[REDACTED]

[REDACTED] *See* TEVA-MDL2875-00734327. This is relevant to demonstrate Teva's corporate knowledge and capabilities.

I. Teva's Motion to Preclude Evidence or Argument About Teva's Reasons for Discontinuing Sales of VCDs

Teva discontinued the at-issue valsartan product in August 2018 in the immediate wake of the recalls. *See, e.g.*, Ex. 21 hereto (FDA Orange Book August 2018 Changes List, showing discontinuation of ANDA#091519 and ANDA#09062, the two Teva ANDAs for VCDs containing valsartan API from ZHP).

Teva implausibly argues this timing is a mere coincidence, and that Teva fortuitously made the decision to stop selling valsartan prior to the recalls. When probed on this specious assertion, Teva's corporate designee could not proffer even the most rudimentary details about this purported pre-recall decision to stop selling valsartan. For instance, Teva's corporate designee could not say who made this purported decision, who was involved in the purported decision, when the purported decision was made, and what documents might memorialize that purported decision. *See* Ex. 22 hereto (Osmian Dep. at 107:18-115:9).

More dubiously, just a few weeks before the recalls, ZHP contacted Teva in May 2018, asking [REDACTED]

[REDACTED]

[REDACTED]. See TEVA-MDL2875-00872512 (Ex. 23 hereto). In fact, when ZHP informed Teva about [REDACTED] [REDACTED]. See, e.g., TEVA-MDL2875-00609197 (Ex. 24 hereto). This is completely inconsistent with Teva's farfetched explanation that it had already decided to stop selling the valsartan product that had incorporated API from ZHP. If Teva already had discontinued sales of VCDs, then [REDACTED] [REDACTED], unless it intended to keep selling VCDs.

All of this evidence is pertinent to the basic facts and timetable for Teva's recalls and when its VCDs were available in the United States market. Further, nothing about these facts, which merely relate to the simple sequence of events, implicates a subsequent remedial measure for purposes of Rule 407 since a business decision unrelated to safety concerns is not remedial. See, e.g., *Brazos v. River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 428-29 (5th Cir. 2006) (Rule 407 does not reach actions unrelated to safety hazards).

J. Teva's Motion to Preclude References to the Timing of Teva's Field Alerts to the FDA

Teva failed to follow cGMPs and its own SOPs requiring the reporting of the NDMA contamination to the FDA. Both FDA regulations and Teva's own SOPs mandate that a firm must notify the FDA within **three days** of a "possible/actual quality issue." See 21 C.F.R. 314.81(b)(1); FDA Form 331A Instructions (2020)

(Ex. 25 hereto); FDA Form 331A Instructions (2017) (Ex. 26 hereto); TEVA-MDL2875-00595257 (Ex. 27 hereto). Teva admittedly did not submit the initial Field Alert Report to the FDA until July 3, 2018 though it was notified of the issue on June 20, 2018. *See* TEVA-MDL2875-00063796 (Ex. 28 hereto).

Teva's corporate representative could not explain why there was a delay in the global quality assurance department being notified that there was a genotoxic impurity in the valsartan when others in the company knew no later than June 20, 2018: [REDACTED]

[REDACTED] Ex.14 (Daniel Barreto Dep. Vol. I at 126:19-127:15).

The delay in notifying the FDA allowed the product that had already been shipped to continue to be sold—rather than triggering a recall that would have required that the product be returned to Teva by its customers, requiring reimbursement. That is not just relevant, it supports Plaintiffs' punitive damages claims. Teva can try to explain away its delay in notifying the FDA but cannot sanitize the trial such that the jury will not know that Teva violated its own cGMP protocol in delaying notice to the FDA while its products continued to be on the market, and in the possession of unwitting patients.

Additionally, although some of the exact dates may be in dispute, for purposes of this motion it suffices to say that ZHP informed Teva about an impurity with

[REDACTED] on or about June 20, 2018. *See, e.g.,* TEVA-MDL2875-00791611 (Ex. 29 hereto). This is when Teva learned, at the latest, of an actual *or possible* quality issue with valsartan API.

Teva, however, claims that ZHP did not specifically identify the impurity as NDMA until June 28, 2018. *See* Teva Mot. at 18. Teva's assertion that it did not know the *actual* quality issue until June 28, and therefore its July 3 Field Alert Report was timely contradicts the FDA regulations and instructions on submissions of field alerts. It also contradicts Teva's own SOPs, which specifically state that [REDACTED]

[REDACTED] *See* TEVA-MDL2875-00595257 (Ex. 27 hereto) [REDACTED]

[REDACTED]).

This evidence of Teva's failure to adhere to cGMP and its own SOPs vis-à-vis at-issue API and finished dose valsartan is highly relevant to Plaintiffs' substantive claims, as well as to punitive damages. Teva's assertion that the FDA never said Teva's Field Alert Report was untimely (*see* Teva Mot. at 19) is a non-sequitur. As the law makes clear (and as the FDA itself has said on innumerable occasions), Teva and other firms may be liable for cGMP violations, adulteration, and other violations of law even if the FDA, with its limited resources, does not catch or cite a firm. Teva's contention that no one was harmed because no product was

purchased after it placed valsartan on hold (*see* Teva Mot. at 18) is inapposite and factually disputed. Whether anyone purchased contaminated Teva product after June 21 (they did) does not inoculate Teva from evidence showing its failure to ascribe to cGMPs and its own SOPs in the immediate wake of the NDMA contamination revelations and recalls.

Even if this were not the case, Teva pulls a bait-and-switch with dates. The document Teva cites does not mention anything about the date Teva placed product on hold in the United States. *See* Teva Ex. X. And, placing a “hold” is not the same as initiating a recall, which Teva did not do until July 16, 2018. *See, e.g.*, Ex. 30 hereto (Teva recall FAQ identifying recall date as July 16, 2018). Thus, even were it pertinent whether some purchasers bought contaminated Teva product between June 21 and July 16, the answer is some did. Or at least, this is a fact question for the jury.

Finally, Teva also unsuccessfully attempted to preclude the opinions of Plaintiffs’ cGMP expert, Philip Russ, about the discrete matter of Teva’s untimely Field Alert Report. The Court rightly rejected that *Daubert* challenge, and allowed all of Mr. Russ’s opinions, including those about the field alert report timing, at trial.

K. Teva’s Motion to Preclude Evidence About Teva’s Valsartan Sales Outside the United States Post-Recall

In this motion, Teva only cites a snippet of deposition testimony about Teva's sale of contaminated valsartan in foreign countries after the 2018 recalls in the United States. *See* Teva Mot. at 20. Plaintiffs therefore confine this response to that particular evidence.

Plaintiffs only intend to use this particular evidence, if at all, to demonstrate Teva's intent, motive, and state of mind, particularly for punitive damages. Plaintiffs do not intend to argue that Teva violated foreign regulations or laws when it sold NDMA-contaminated valsartan in other countries. Nor do Plaintiffs seek damages for valsartan sold by Teva in foreign countries. But Teva's attempt to dump contaminated valsartan into the markets of other countries that had yet to catch up with the rest of world about nitrosamines because Teva could no longer sell this product in the United States (*see, e.g.*, TEVA-MDL2875-00024041 (Ex. 31 hereto); TEVA-MDL2875-0045893 (Ex. 32 hereto)), is probative of Teva's profits-over-people mindset. Punitive damages is a proper purpose for such evidence. *See, e.g., Sanders v. Jersey City*, No.18-01057, 2021 WL 1589464, at *26 n.19 (D.N.J. Apr. 23, 2021) (denying summary judgment on punitive damages claim because fact dispute existed on defendants' mindsets).

L. Teva's Motion to Preclude Reference to its Destruction of Recalled Valsartan Finished Dose or API

At summary judgment, Teva's response to Plaintiffs' statement of undisputed material facts appeared to suggest Teva might oppose at trial the notion that NDMA

was in all of the ZHP valsartan API that Teva purchased and incorporated into its own finished dose, and correspondingly in all of Teva's own valsartan finished dose. *See, e.g.*, ECF 2602 at ¶¶ 10-12. If Teva planned to challenge at trial whether its VCDs contained NDMA and at what levels, then it becomes highly relevant that Teva anxiously [REDACTED]

[REDACTED] *See, e.g.*, Barreto Dep. Vol. II at 616:9-617:9, 620:16-621:8, 621:22-628:15, 634:1-650:7, 651:19-661:22, 664:9-665:11, 668:20-669:14, 681:11-22 (Ex. 33 hereto). Teva should not be able to assert that every lot of recalled valsartan API and finished dose was not contaminated with NDMA, on the one hand, while [REDACTED] [REDACTED] on the other.

Teva's instant motion, however, makes clear that Teva agrees all of its valsartan finished dose containing [REDACTED] [REDACTED] Teva. Mot. at 22. Elsewhere, Teva's corporate designees have confirmed that [REDACTED] [REDACTED]. *See* Barreto Dep. Vol. I at 201:10-202:9, 275:25-276:5, 367:19-368:2 (Ex. 15 hereto).

Therefore, it likely will be unnecessary for Plaintiffs to put on affirmative evidence of Teva's destruction of recalled or unsaleable valsartan API or finished dose, with two potential and discrete exceptions. One is, **to the extent Teva**

destroyed the product because it was unsaleable, that in itself is probative of **Plaintiffs’ worthlessness theory**. The second is that Teva’s impatience to destroy the product notwithstanding a litigation hold goes to the egregiousness of Teva’s conduct and punitive damages. Again, this was not “routine” destruction, as Teva suggests. *See* Teva Mot. at 22. Rather, Teva peppered [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *See*, e.g., Barreto Dep. Vol. II at 616:9-617:9, 620:16-621:8, 621:22-628:15, 634:1-650:7, 651:19-661:22, 664:9-665:11, 668:20-669:14, 681:11-22 (Ex. 33 hereto). At a minimum, these events underscore the insufficiency of Teva’s quality procedures.

Plaintiffs can and should be permitted to present discrete evidence of Teva’s destruction of product on these two highly relevant, non-prejudicial points.

II. CONCLUSION

For the foregoing reasons, Teva’s omnibus motions in limine should be denied.

Dated: February 26, 2024

/s/ Ruben Honik

Respectfully submitted,

/s/ Daniel Nigh

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CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2024, a true and correct redacted copy of the foregoing was filed and served via the Court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch

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